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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

09/10/2009

Johnson & Johnson
International Patent Law Division
P.O. Box 1222
New Brunswick, NJ 08901

EXAMINER

NGHEM, MICHAEL P

ART UNIT

PAPER NUMBER

2863

DATE MAILED: 09/10/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,586	04/26/2006	Oliver William Davies	D5015/USP	3793

TITLE OF INVENTION: METHOD OF REDUCING THE EFFECT OF DIRECT INTERFERENCE CURRENT IN AN ELECTROCHEMICAL TEST STRIP

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/10/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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09/10/2009

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DI5015/USP

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TITLE OF INVENTION: METHOD OF REDUCING THE EFFECT OF DIRECT INTERFERENCE CURRENT IN AN ELECTROCHEMICAL TEST STRIP

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/10/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGHIEM, MICHAEL P	2863	702-022000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/577,586

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Oliver William Davies

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EXAMINER

NGHIEM, MICHAEL P

ART UNIT

PAPER NUMBER

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DATE MAILED: 09/10/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/577,586

Applicant(s)

DAVIES ET AL.

Examiner

MICHAEL P. NGHIEM

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Communication filed on 26 August 2009.
2. ☒ The allowed claim(s) is/are 1-10.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2009 has been entered.

Information Disclosure Statement

The information disclosure statement filed on August 26, 2009 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. Search

Reports and Written Opinions are not listed. Furthermore, NPL reference Matsue et al., "Multichannel electrochemical detection system for flow analysis" is not listed. It is noted that the references cited in the Search Reports and Written Opinions have been listed in prior IDS's. NPL reference Matsue et al. is now listed in the Notice of References Cited, form PTO-892.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by Mr. Khoi Ta during a telephone interview on August 31, 2009.

The application has been amended as follows:

In the specification:

Paragraph 00074, line 9, after "10/143,399", insert -- , now abandoned --.

Replace Claim 1 with the following:

-- 1. (Currently Amended) A method of reducing interferences in an electrochemical sensor comprising:

measuring a first current using a first working electrode, said first working electrode having an area being covered by a reagent layer;

measuring a second current using a second working electrode having a covered area coated by the reagent layer and an uncovered area not coated by the reagent layer such that intereferent current produced at the uncovered area is proportional to interferent current produced overall; and

calculating, by a meter, a corrected current value representative of a glucose concentration using the measured first current, the measured second current, and a ratio of said covered area to said uncovered area of said second working electrode to reduce the effects of interferents. --

Replace Claim 3 with the following:

-- 3. (Currently Amended) A method of reducing interferences in an electrochemical sensor comprising:

measuring a first current using a first working electrode, wherein said reagent layer partially covers said first working electrode, said first working electrode having a first coated area covered by said reagent layer and a first uncoated area not covered by said reagent layer;

measuring a second current using a second working electrode, wherein said reagent layer partially covers said second working electrode, said second working electrode having a second covered area coated by said reagent layer and a second

uncovered area not coated by said reagent layer such that interferent current produced at the uncovered area is proportional to interferent current produced overall; and

calculating, by a meter, a corrected current value representative of a glucose concentration using the measured first current, the measured second current, and a ratio of said covered area to said uncovered area of said first and said second working electrodes to reduce the effects of interferents. --

Replace Claim 7 with the following:

-- 7. (Currently Amended) A method of reducing interferences in an electrochemical sensor having a first and second working electrodes disposed on a substrate and an insulation disposed over electrodes and the substrate, the insulation having an opening to allow a reagent to contact portions of the first and second working electrodes, the method comprising:

measuring a first current using a first working electrode, said first working electrode having an area coated by the reagent;

measuring a second current using a second working electrode having an area coated by the reagent and an area uncoated by the reagent such that interferent current produced at the uncoated area is proportional to interferent current produced overall; and

calculating, by a meter, a corrected current value representative of a glucose concentration using the measured first current, the measured second current, and a

ratio of said coated area to said uncoated area of said second working electrode to reduce the effects of interferents. --

Replace Claim 9 with the following:

-- 9. (Currently Amended) A method of reducing interferences in an electrochemical sensor having a first and second working electrodes disposed on a substrate and an insulation disposed over electrodes and the substrate, the insulation having an opening to allow a reagent to contact portions of the first and second working electrodes, the method comprising:

measuring a first current using a first working electrode having a first coated area covered by the reagent and a first uncoated area not covered by the reagent;

measuring a second current using a second working electrode having a second covered area coated by said reagent and a second uncovered area not coated by said reagent such that intereferent current produced at the uncovered area is proportional to interferent current produced overall; and

calculating, by a meter, a corrected current value representative of a glucose concentration using the measured first current, the measured second current, and a ratio of said covered area to said uncovered area of said first and said second working electrodes to reduce the effects of interferents. --

Reasons For Allowance

The **combination** as claimed wherein a method for reducing interferences in an electrochemical sensor comprising calculating, by a meter, a corrected current value representative of a glucose concentration using a measured first current, a measured second current, and a ratio of a covered area to an uncovered area of a second working electrode (claims 1, 3, 7, 9) is not disclosed, suggested, or made obvious by the prior art of record.

Rappin et al. (US 2005/0157947) discloses a sensor for determining various concentrations of components within a fluid sample (Abstract, lines 1-2), a meter is attached to the sensor for measuring the electrochemical changes occurring in the reaction zone (Abstract, lines 10-13).

Winarta et al. (US 6,287,451) discloses a disposable electrode strip comprising a reference electrode and at least two working electrodes for testing a fluid sample (Abstract, lines 1-5). One of the working electrode contains a reagent similar to the reagent of the reference electrode and a second working electrode contains a reagent having an enzyme (Abstract, lines 13-16).

Hintsche et al. (US 5,830,343) discloses a process for performing electrochemical analysis of compounds of solutions using electrodes (Abstract, lines 1-8).

Carter et al. (US 5,628,890) discloses an electrode strip for use in an electrochemical sensor for measuring a compound in a sample, the strip includes a reference electrode and a working electrode (Abstract, lines 1-5).

Braden et al. (US 5,298,146) discloses a device for detection of dissimilar gas components containing a number of working electrodes and a reference electrode (Abstract, lines 1-6).

Bae et al. (WO 2004/029605) discloses an apparatus and a method for determining whether or not a biosensor comprising two working electrodes and one reference electrode is well manufactured and for quantifying a substance in a biological sample (Abstract, lines 1-5).

Harman (WO 89/02593) discloses a method and apparatus for electrochemical determination of an electrochemical reactive substance in a fluid stream (Abstract, lines 1-2).

Harrington et al., "Multiple electrode potentiostat", discloses a general purpose multiple electrode potentiostat that measures currents at multiple working electrodes using a single auxiliary electrode and a reference electrode (Abstract, lines 1-4).

However, none of the above references teaches calculating, by a meter, a corrected current value representative of a glucose concentration using a measured first current at a first electrode, a measured second current at a second electrode, and a ratio of a covered area to an uncovered area of a second working electrode

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P Nghiem whose telephone number is (571) 272-2277. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on (571) 272-2312. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael P. Nghiem/

Primary Examiner, GAU 2863

August 31, 2009